K053310

510(k) SUMMARY

Submitter's Information	VasCon LLC 9344 NW 13 Street Miami, Florida 33172 USA Telephone: 1.305.477.2406 Fax: 1.305.592.6605 Contact: Stephen F. Vadas, Ph.D.
Preparation Date	18 November 2005
Name of Device	Classification Name: Continuous Flush Catheter Trade Name: VasCon Roamer Microcatheter
Predicate Device	Cordis Catheters (MassTransit®, Prowler® Plus, and the Prowler® 14)
Intended Use	The VasCon Roamer Microcatheters are indicated for the selective infusion of various diagnostic, therapeutic, and embolic agents into the peripheral, coronary, and neurovasculature.
Device Description and Summary of Technological Characteristics	The VasCon Roamer Microcatheters are single lumen catheters, incorporating a Pebax body reinforced with stainless steel and platinum wire, a PTFE lubricious inner lumen, and a soft radiopaque tip to reduce potential vessel injury. They are available in French sizes of 2.3/1.9, 2.8/2.3, 3.0/2.8, 2.4/2.0, and 2.8/2.7 and in lengths of 105 cm, 135 cm, and 150 cm. The inside diameters are 0.017, 0.019, 0.021, and 0.027 inches. They have a hydrophilic coating to provide lubricity during use. The technological characteristics are equivalent to the predicate device.
Testing Summary	Laboratory testing has been performed on the VasCon Roamer Microcatheter to assure compliance to the specifications. In addition, laboratory testing has been performed on the materials to assure biocompatibility.
Conclusions	The testing as discussed above demonstrates that, like the predicate devices, the VasCon Roamer Microcatheters are safe and effective for its intended use.

JUL - 3 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

VasCon LLC
c/o Stephen F. Vadas, PhD
Vice President
9344 NW 13th Street
Miami, FL 33172

JUL - 3 2008

Re: K053310
Trade/Device Name: VasCon Roamer Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: catheter, continuous flush
Regulatory Class: Class II
Product Code: KRA
Dated: March 12, 2008
Received: April 7, 2008

Dear Dr. Vadas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053310

Device Name: VasCon Roamer Microcatheter

Indications For Use:

The VasCon Roamer Microcatheters are indicated for the selective infusion of various diagnostic, therapeutic, and embolic agents into the peripheral, coronary, and neurovasculature.

Prescription Use___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053310